

Appl. No. 10/533,749  
Amdt. Dated May 21, 2008  
Reply to Office Action of December 21, 2007

**Amendment to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1. (currently amended): A catheter-flushing system for maintaining the patency of a lumen of an indwelling catheter, the catheter lumen having an indwelling portion beneath the skin of a patient, the system comprising:
  - a. a patient mounted tubing system comprising a single extension tube in fluid connection with the indwelling portion, the tubing system defining an internal volume and at least one proximal terminal for intermittent connection with an external fluid source of flush solution, the proximal terminal including a seal for promptly sealing upon disconnection of the source, so that at least a portion of the flush solution entering the tubing system through the terminal remains sealed within the tubing system after the source has been disconnected from the system, thereby defining a residual volume of flush solution within the tubing system,
  - b. ~~a~~ at least one volume reducer for connection with the system and for progressively reducing the internal volume at a plurality of different times, to

- c. displace a plurality of fractions of the residual volume into the indwelling portion to intermittently flush the indwelling portion with the flush solution.
2. (previously presented): The catheter-flushing system of claim 1, wherein the flush solution is saline.
3. (previously presented): The catheter flushing system of claim 1, wherein the flush solution is a mixture of diluent and at least one of an anticoagulant and an antimicrobial agent.
4. (currently amended): The catheter flushing system of claim 3, further wherein the volume ~~reducer~~ reducers are is comprised of a plurality of clamps.
5. (currently amended): The catheter flushing system of claim 1, wherein the volume ~~reducer~~ reducers are is mounted with the tubing system.
6. (currently amended): The catheter flushing system of claim 1, wherein activation of the volume ~~reducer~~ reducers reduces the volume within the tubing system by at least one discrete volume.

7. (currently amended): The catheter flushing system of claim 1, wherein a plurality of activations of the volume ~~reducer~~ reducers reduces the volume within the tubing system by a plurality of discrete volumes at a plurality of different times to provide intermittent flushing of the catheter portion over a prolonged time interval.

8. (currently amended): A patient mounted system for providing intermittent bolus injection of a flush solution through an indwelling catheter to intermittently flush the lumen of the catheter, the system comprising:

a. a single extension tube for mounting with a patient, the tube having a distal end connectable to the catheter and at least one proximal end with a terminal for intermittent connection with a source of flush solution, the terminal including a seal for sealing the proximal end of the tube when the source of flush solution is disconnected from the terminal, the tube further defining an internal open space defining a variable internal volume and a lumen extending therethrough from the sealed proximal terminal to the distal end, so that when a source of flush solution is connected to the terminal, flush solution can enter the tube from the source through the terminal and flow through the lumen to at least partially fill ~~said~~ the internal space, the lumen defining at least a portion of the internal volume,

b. ~~a volume reducer~~ a plurality of volume reducers comprised of at least one volume reducing element mounted with ~~said~~ the system, the volume reducer being configured for sequentially reducing the internal volume of the tube at a plurality of different times after the distal end has been connected with the catheter, the flush solution has been flowed into the space from the source, and the source has been disconnected from ~~said~~ the terminal.

9. (previously presented): The system of claim 8, wherein the tube is elongated.

10. (previously presented): The system of claim 8, wherein the tube is flexible.

11. (currently amended): The system of claim 8 wherein the ~~reducer~~ reducers are is a clamp mounted with the tube.

12. (currently amended): The system of claim 8, wherein the ~~reducer~~ reducers are is comprised of a plurality of reducing elements.

13. (previously presented): The system of claim 12, wherein the elements comprise clamps mounted with the tube.

14. (currently amended): The system of claim 11, wherein the ~~clamp is~~ clamps are a

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pinch ~~elamp~~-clamps.

15. (currently amended): The system of claim 11, wherein the ~~elamp defines~~ clamps define at least one elongated opposing surface for compressing the tube.

16. (currently amended): The system of claim 11, wherein the ~~elamp defines~~ clamps define opposing elongated opposing surfaces for compressing the tube.

17. (previously presented): The system of claim 8, wherein the tube defines at least one internal diameter and wherein the diameter is variable.

18. (previously presented): The system of claim 8, wherein the tube defines at least one internal diameter and includes an enlarged portion having an increased internal diameter adjacent at least one element.

19. (currently amended): A medical device for administration of fluid to a patient comprising:

a. a patient mounted, fluid-lock system having a distal portion for insertion into a blood vessel to define an indwelling portion, the system having a single extension tube having an internal space defining an internal volume, the pressure within the space being

essentially equal to the pressure in the blood vessel when the indwelling portion resides within the blood vessel, the system further having at least one proximal terminal for intermittent connection with an external fluid source of flush solution, the proximal terminal including a seal for sealing upon disconnection of the source, so that at least a portion of the flush solution entering the fluid-lock system through the terminal from the source remains sealed within the fluid-lock system after the source has been disconnected from the fluid-lock system, thereby defining a residual volume of flush solution within the fluid-lock system,

- b. ~~a volume reducer~~ a plurality of volume reducers for engaging the system and for progressively reducing the volume of flush solution contained within the space by facilitating the movement of at least sequential portions of the flush solution into the blood vessel[[.]], wherein at least one volume reducer is configured to reduce the volume of the single extension tube a first time, to thereby define a first residual volume of the extension tube, and wherein, prior to refilling of the extension tube, at least one volume reducer is further configured to reduce the volume of the single extension tube a second time to thereby define a second residual volume of the extension tube, the second residual volume of the extension tube being less than the first residual volume of the extension tube.

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20. (currently amended): The medical device of claim 19, wherein the volume ~~reducer~~ reducers are is configured to progressively reduce the internal volume at a plurality of different times, to displace a plurality of fractions of the residual volume into the indwelling portion to intermittently flush the indwelling portion with the flush solution.

21. (previously presented): The medical device of claim 19, wherein the distal portion is a catheter.

22. (previously presented): The medical device of claim 19, wherein the tube defines at least a portion of the internal space.

23. (currently amended): The medical device of claim 22, wherein the volume ~~reducer~~ reducers are is mounted with the tube.

24. (currently amended): The medical device of claim 22, wherein the volume ~~reducer~~ reducers are is configured to reduce the volume of the tube.

25. (currently amended): The medical device of claim 22, wherein the volume ~~reducer~~ reducers are is configured to progressively reduce the volume within the tube by a plurality of discrete volumes.

26. (currently amended): The medical device of claim 19, wherein the volume ~~reducer~~ reducers are is configured to progressively reduce the volume within the tube by a plurality of substantially equal volumes.

27. (currently amended): A system for maintaining at least one of the patency and sterility of the lumen of a catheter, the system within the blood vessel of a patient, the blood vessel containing flowing blood, the lumen defining a distal end within the blood vessel, the system comprising:

a. a mixture of a diluent and at least one of an anticoagulant and an antimicrobial ~~the mixture of at least one antimicrobial and anticoagulant,~~

b. a reservoir fluid-locked with the catheter for storing the mixture, the reservoir being in fluid communication with a blood vessel through the lumen, the reservoir defining an internal space filled with the mixture, the space having a an internal pressure essentially equal to the pressure within the blood vessel, such that the mixture within the lumen interfaces with blood within the blood vessel at a mixture-to-blood interface adjacent the distal end of the lumen,

c. ~~a volume reducer~~ a plurality of volume reducers configured for engaging sequential portions of the reservoir and for sequentially reducing the volume of



the mixture contained within the space to cause the movement of at least sequential portions of the mixture into the interface to increase the concentration of the mixture along the interface.

28. (currently amended): The system of claim 27, wherein the volume reducer includes at least one element for reducing the volume of the reservoir by predetermined discrete and limited increments at a plurality of different times to increase the efficacy of the mixture with a minimum of transfer of the mixture into the ~~patients~~ patient's blood vessel.

29. (currently amended): A system for maintaining at least one of the patency and sterility of the lumen of a catheter[,], the system within the blood vessel of a patient, the blood vessel containing flowing blood, the lumen defining a distal end within the blood vessel, the system comprising:

a. a flush solution,

b. a reservoir comprising a single extension tube fluid-locked with the catheter lumen for storing the flush solution, the reservoir being in fluid communication with a blood vessel through the lumen, the reservoir defining an internal space substantially filled with the flush solution and the space having a an internal pressure essentially equal to the

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pressure within the blood vessel, such that the flush solution within the lumen interfaces with blood within the blood vessel at a solution-to-blood interface adjacent the distal end of the lumen,

c. ~~a volume reducer~~ a plurality of volume reducers for engaging the reservoir and for reducing the volume of the flush solution contained within the space by facilitating the movement of at least a portion of the flush solution into the interface to increase the concentration of the solution along the interface, the volume reducer including at least one element configured for sequentially reducing the volume of the reservoir by predetermined discrete and limited increments at a plurality of different times to increase the efficacy of the flush solution with a minimum of transfer of the flush solution into the ~~patients~~ patient's blood vessel~~[[.]]~~, wherein at least one volume reducer is configured to reduce the volume of the single extension tube a first time, to thereby define a first residual volume of the extension tube, and wherein, prior to refilling of the extension tube, at least one volume reducer is further configured to reduce the volume of the single extension tube a second time to thereby define a second residual volume of the extension tube, the second residual volume of the extension tube being less than the first residual volume of the extension tube.

30. (currently amended): A method for intermittently flushing the lumen of an

indwelling catheter with fluid comprising flush solution derived from an external fluid source when the catheter is no longer in fluid communication with the external fluid source, the catheter lumen having an indwelling portion beneath the skin of a patient and extending into a blood vessel, the method comprising steps of:

a. disposing a patient mounted tubing system comprising a single extension tube in fluid connection with the indwelling portion, the tubing system defining an internal volume and at least one proximal terminal,

b. flowing flush solution from the external fluid source, through at least one terminal and through the tubing system into the indwelling portion, at least a portion of the solution at least partially filling the internal volume, promptly sealing the proximal terminal of the tubing system such that at least a portion of the flush solution remains sealed within the tubing system thereby defining a residual volume of flush solution within the tubing system, and

c. progressively reducing the internal volume of the tubing system to displace at least sequential portions of the residual volume into the indwelling portion to intermittently flush the indwelling catheter portion with the flush solution[[]] wherein the steps of progressively reducing comprises reducing the volume of the single extension tube a first time, to thereby define a first residual volume of the extension tube, and reducing the

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volume of the single extension tube a second time to thereby define a second residual volume of the extension tube, the second residual volume of the extension tube being less than the first residual volume of the extension tube.

31. (currently amended): A method for intermittently flushing the lumen of an indwelling catheter with flush solution derived from an external fluid source when the catheter is no longer in fluid communication with the external fluid source, the catheter having a an indwelling portion defining a lumen beneath the skin of a patient the lumen extending into a blood vessel and being in fluid connection with the blood vessel, the method comprising steps of:

a. disposing a single extension tube in fluid connection with the lumen of the indwelling portion of the catheter, the single extension tube system defining an internal volume and at least one proximal terminal,

b. flowing flush solution from the external fluid source, through ~~the~~ at least one terminal and into the extension tube, at least a portion of the solution at least partially filling the extension tube,

c. sealing the proximal terminal of the extension tube such that at least a portion of the flush solution remains sealed within the extension tube thereby defining a residual volume of flush solution within the extension tube, and

d. sequentially reducing the internal volume of the extension tube a plurality of different times to displace sequential portions of the residual volume of the flush solution into the lumen to flush the lumen with the flush solution so that patency of the lumen is maintained for an extended period of time[[]], wherein the steps of sequentially reducing comprises reducing the volume of the single extension tube a first time, to thereby define a first residual volume of the extension tube, and without refilling the extension tube, reducing the volume of the single extension tube a second time to thereby define a second residual volume of the extension tube, the second residual volume of the extension tube being less than the first residual volume of the extension tube.

32. (currently amended): A method for intermittently flushing the lumen of an indwelling catheter with flush solution derived from an extension tube in fluid connection with the catheter, the extension tube defining an internal volume and having a sealed proximal terminal[,], the method comprising steps of[[]] [:]

a. injecting flush solution into the extension tube through the sealed proximal terminal to define an initial volume of flush solution within the extension tube,

b. after a first delay of a at least several hours, reducing the internal volume of the extension tube a first time to force flush solution distally out of the extension tube and along the lumen, thereby defining a first residual fluid volume of flush solution within the extension tube after the internal volume of the extension tube has been reduced the first time, the first residual fluid volume being less than the initial volume,

c. after a second delay of at least several hours[, ] again reducing the internal volume of the extension tube a second time to force flush solution distally, out of the extension tube and along the lumen, thereby defining a second residual volume of flush solution within the extension tube after the internal volume has been reduced the second time, the second residual volume being less than the first residual volume,

d. after a third delay of at least several hours[, ] again reducing the internal volume of the extension tube a third time to force flush solution distally, out of the extension tube and along the lumen, thereby defining a third residual volume of flush solution within the extension tube after the internal volume has been reduced the third time, the third residual volume being less than the second residual volume.

33. (previously presented): The method of claim 32 wherein, reducing the volume of the extension tube a first time comprises compressing the extension tube.

34. (previously presented): The method of claim 32 wherein, reducing the volume of the extension tube a first time, a second time, and a third time comprises compressing the extension tube a first time, a second time, and a third time respectively.

35. (currently amended): A method of maintaining the patency of a lumen of an indwelling catheter over a 24-72 hour period, the lumen being connected with a single fluid locked extension tube filled with flush solution, the extension tube defining an internal volume, the method comprising steps of; sequentially reducing the internal volume of the extension tube a plurality of different times to express sequential portions of the flush solution from the extension tube into the lumen to sequentially flush the lumen at a plurality of different times[[.]], wherein the steps of sequentially reducing comprises reducing the volume of the single extension tube a first time, to thereby define a first residual volume of the extension tube, and without refilling the extension tube, reducing the volume of the single extension tube a second time to thereby define a second residual volume of the extension tube, the second residual volume of the extension tube being less than the first residual volume of the extension tube.

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36. (previously presented): The method of claim 35 wherein the steps of sequentially reducing the volume of the extension tube comprises sequentially compressing the extension tube.